IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI

DIANE KROPF and JOSEPH KROPF,	)	
	)	
Plaintiffs,	)	
	)	CIVIL ACTION FILE
v.	)	
	)	NO. _____
JOHNSON & JOHNSON, ETHICON, INC., AND JOHN DOE CORPORATIONS 1-50 (fictitious),	)	
	)	
	)	
Defendants.	)	
_____	)	

COMPLAINT

COME NOW Diane and Joseph Kropf as Plaintiffs herein and hereby file this Complaint, showing the Court as follows:

PARTIES, JURISDICTION AND VENUE

1. Plaintiffs are citizens of the State of Virginia. Hereinafter Plaintiff Diane Kropf will be referred to individually as Plaintiff.

2. Defendant Johnson & Johnson, Inc. is a corporation existing under the laws of the State of New Jersey, with its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey.

3. Defendant Ethicon, Inc., a subsidiary of Defendant Johnson & Johnson, Inc., is a corporation existing under the laws of New Jersey, with its principal place of business at Route 22 West, Somerville, New Jersey.

4. Defendant John Doe Corporations 1-50 represent presently unknown designers, researchers, developers, manufacturers, marketers, distributors, promoters, suppliers, and sellers of the Gynecare Prolift and the Gynecare TVT which was and is defective and unreasonably dangerous to women.

5. Plaintiffs are seeking damages in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

6. Defendant is registered to do business in Missouri, maintains its registered agent as CSC-Lawyers Incorporating Service Company, 221 Bolivar Street, Jefferson City, Missouri 65101, and is subject to the personal jurisdiction of this Court.

7. Pursuant to 28 U.S.C. § 1391(a), venue is proper in the Western District of Missouri.

FACTUAL BACKGROUND

8. At all relevant times, Defendants Johnson & Johnson, Ethicon, Inc., and John Doe Corporations 1-50 (collectively "Defendants") were in the business of and did create, design, manufacture, test, formulate, advertise, market, promote, sell and/or distribute the Gynecare Prolift, designed to treat pelvic organ prolapse. The Prolift was and is offered as an anterior, posterior or total repair system, and all references to the Prolift include all variations.

9. At all relevant times, Defendants were in the business of and did create, design, manufacture, test, formulate, advertise, market, promote, sell and/or distribute the

Gynecare TVT, designed to treat urinary incontinence. The TVT was and is offered in multiple variations including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT include all variations.

10. The Prolift and the TVT will collectively be referred to as "Products."

11. On or about April 5, 2010, Plaintiff was implanted with Defendants' Products by Dr. Patricia Murray at Mary Washington Hospital located in Fredericksburg, Virginia.

12. The Products were implanted in Plaintiff to treat her pelvic organ prolapse and urinary incontinence, the use for which Products were designed, marketed and sold.

13. Due to the Products' defects, Defendants' negligence, and Defendants' breach of express and implied warranties as described herein, Plaintiff has suffered severe and permanent bodily injuries and significant mental and physical pain and suffering, and economic losses.

14. Defendants sought and obtained FDA clearance to market the Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to either of the Products.

15. On October 20, 2008 the FDA issued a public health notification alerting the medical community that transvaginal placement of mesh device systems, including the Products, could lead to potentially serious complications including erosion of the material, infection, pain, urinary complications, and recurrence of prolapse or incontinence.

16. In a study published in August 2010 in the Journal of the American College of Obstetricians and Gynecologists, it was concluded that there is a high (15.6%) vaginal mesh erosion rate with the Prolift, "with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs." Numerous studies published in influential medical journals have reached similar conclusions.

17. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

18. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

19. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

20. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

21. Plaintiff's injuries are consistent with complications reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

22. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

23. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

24. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper").

In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

25. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

26. The FDA White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

27. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

28. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

29. Defendants knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

30. Defendants knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

31. The scientific evidence shows that the polypropylene material from which the Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including Plaintiff.

32. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

33. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Products were unreasonably susceptible to degradation and fragmentation inside the body.

34. The Products were unreasonably susceptible to shrinkage and contraction inside the body.

35. The Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

36. The Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

37. Defendants omitted the risks, dangers, defects, and disadvantages of the Product, and advertised, promoted, marketed, sold and distributed the Products as a safe medical device when Defendants knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries.

38. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making it defective under the law.

39. The specific nature of the Products' defects includes, but is not limited to, the following:

a. the use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Products to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where it is implanted,

and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time.

40. The Products are also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. the need for corrective or revision surgery to adjust or remove the Products;

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

41. Defendants have underreported information about the propensity of the Products to fail and cause injury and complications, and have made unfounded

representations regarding the efficacy and safety of the Products through various means and media.

42. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Products.

43. Defendants failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

44. Feasible and suitable alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Product.

45. The Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

46. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

47. The Products implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

48. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited

to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

49. In many cases, including Plaintiff's, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

50. The medical and scientific literature studying the effects of polypropylene mesh, like that of the Products, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

51. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

52. At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

53. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

54. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

55. The Products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

56. As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

CAUSES OF ACTION

COUNT I: NEGLIGENCE

57. Plaintiffs incorporate by reference paragraphs 1-56 of this Complaint as if fully set forth herein.

58. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

59. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendants breached their aforementioned duty by:

a. Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Products.

60. The reasons that Defendants' negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time.

61. Defendant also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. the need for corrective or revision surgery to adjust or remove the Product;

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

62. As a direct and proximate result of Defendants' negligence, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

63. Plaintiffs incorporate by reference paragraphs 1-62 of this Complaint as if fully set forth herein.

64. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a. the use of polypropylene material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products to "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and

causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time.

65. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

66. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling defective products.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

67. Plaintiffs incorporate by reference paragraphs 1-66 of this Complaint as if fully set forth herein.

68. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as described herein as a matter of law with respect to their manufacture, in that it deviated materially from Defendants' design and

manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to said Plaintiff.

69. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

70. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT IV: STRICT LIABILITY – FAILURE TO WARN

71. Plaintiffs incorporate by reference paragraphs 1-70 of this Complaint as if fully set forth herein.

72. The Products implanted in Plaintiff were not reasonably safe for their intended use and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. the Products' propensity to contract, retract, and/or shrink inside the body;

b. the Products' propensity for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. the need for corrective or revision surgery to adjust or remove the Products;

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

73. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

74. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT V: BREACH OF EXPRESS WARRANTY

75. Plaintiffs incorporate by reference paragraphs 1-74 of this Complaint as if fully set forth herein.

76. Defendants made assurances as described herein to the general public, hospitals and health care professionals that the Products were safe and reasonably fit for their intended purposes.

77. Plaintiff and/or her healthcare provider chose the Products based upon Defendants' warranties and representations as described herein regarding the safety and fitness of the Products.

78. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' express warranties and guarantees that the Products were safe, merchantable, and reasonably fit for their intended purposes.

79. Defendants breached these express warranties because the Products implanted in Plaintiff were unreasonably dangerous and defective as described herein and not as Defendants had represented.

80. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

81. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT VI: BREACH OF IMPLIED WARRANTY

82. Plaintiffs incorporate by reference paragraphs 1-81 of this Complaint as if fully set forth herein.

83. Defendants impliedly warranted that the Products were merchantable and were fit for the ordinary purposes for which they were intended.

84. When the Product was implanted in Plaintiff to treat her pelvic organ prolapse, the Product was being used for the ordinary purposes for which it was intended.

85. Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Products implanted in her.

86. Defendants breached these implied warranties of merchantability because the Products implanted in Plaintiff were neither merchantable nor suited for their intended use as warranted.

87. Defendants' breach of its implied warranties resulted in the implantation of unreasonably dangerous and defective products in Plaintiff's body, placing said Plaintiff's health and safety in jeopardy.

88. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo corrective surgery and hospitalization, has suffered

financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT VII: LOSS OF CONSORTIUM

89. Plaintiffs incorporate by reference paragraphs 1-88 of this Complaint as if fully set forth herein.

90. As a direct and proximate result of the above-described injuries sustained by Plaintiff, her husband, Plaintiff Joseph Kropf, has suffered a loss of his wife's consortium, companionship, society, affection, services and support.

COUNT VIII: PUNITIVE DAMAGES

91. Plaintiffs incorporate by reference paragraphs 1-90 of this Complaint as if fully set forth herein.

92. Defendants sold the Products to Plaintiff's healthcare providers and other healthcare providers throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

93. Defendants sold the Products to Plaintiff's health care providers and other health care providers throughout the United States in spite of their knowledge that the Products can shrink and/or degrade inside the body, thereby causing severe and debilitating injuries suffered by Plaintiff and numerous other women.

94. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Products' failures to perform as

intended, which lead to the severe and debilitating injuries suffered by Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Products as safe and effective.

95. Defendants knew the Products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Products, as well as other severe and personal injuries which were permanent and lasting in nature.

96. Defendants withheld material information from the medical community and the public in general, including Plaintiff, regarding the safety and efficacy of the Products.

97. Defendants knew and recklessly disregarded the fact that the Products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse.

98. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Products.

99. Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risks associated with the Products.

100. Defendants knew of the Products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff.

101. Defendants continue to conceal and/or fail to disclose to the public, including Plaintiff, the serious complications associated with the use of the Products to ensure continued and increased sales of the Products.

102. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand a trial by jury, judgment against Defendants for compensatory and punitive damages in an amount exceeding $75,000, as well as costs, attorney fees, interest, or any other relief, monetary or equitable, to which they are entitled.

PLAINTIFFS DEMAND A TRIAL BY JURY.

Dated: April 2, 2012

Respectfully submitted,
s/ Derek H. Potts

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